NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE LLC et al., Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC et al., Defendants.	:	Civil Action No. 11-3781 (SRC) **OPINION**

CHESLER, District Judge

This matter comes before this Court on six motions for summary judgment, pursuant to Federal Rule of Civil Procedure 56: 1) the motion for partial summary judgment of anticipation of claims 1, 2, and 5 of U.S. Patent No. 7,662,787 by Defendants Actavis Elizabeth LLC, Actavis LLC, Amneal Pharmaceuticals, LLC, Johnson Matthey Inc., Johnson Matthey Pharmaceutical Materials, Mylan Inc., Mylan Pharmaceuticals, Inc., Roxane Laboratories Inc., and Sandoz Inc. (collectively, "Defendants"); 2) Defendants' motion for partial summary judgment of noninfringement; 3) Defendants' motion for partial summary judgment of invalidity under 35 U.S.C. § 101; 4) Defendants' motion for partial summary judgment of no willful infringement; 5) the motion for partial summary judgment of no indirect infringement by Defendants Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials; and 6) the motion for summary judgment that claims of the '630, '787, '253, and '486 patents are infringed and not invalid by Plaintiffs Shire LLC and Shire Development LLC (collectively, "Plaintiffs"). For the reasons stated below, Defendants' motion for partial summary judgment of noninfringement and

Defendants' motion for partial summary judgment of no willful infringement will be granted, Plaintiffs' motion for summary judgment that claims of the '630, '787, '253, and '486 patents are infringed and not invalid will be granted in part and denied in part, and the remaining motions will be denied.

BACKGROUND

This is a Hatch-Waxman case involving a patent dispute between Plaintiffs, holders of patents protecting their marketing of lisdexamfetamine dimesylate[1] under the name of Vyvanse®, and Defendants, which include the "ANDA Defendants" (Defendants Actavis Elizabeth LLC, Actavis LLC, Amneal Pharmaceuticals, LLC, Mylan Inc., Mylan Pharmaceuticals, Inc., Roxane Laboratories Inc., and Sandoz Inc.), which are generic pharmaceutical companies who have filed ANDA applications seeking to market generic lisdexamfetamine dimesylate. Defendants also include Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials (collectively, "JM"), a supplier of lisdexamfetamine dimesylate to the ANDA Defendants, but not an ANDA applicant. The case involves 18 patents and over 400 asserted claims; a much smaller subset of claims and patents are at issue in the present motions.

APPLICABLE LEGAL STANDARDS

I. Motion for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S.

[1] The patents in suit refer to the compound L-lysine-d-amphetamine, and its mesylate salt, L-lysine-d-amphetamine dimesylate. The parties have also used the terms "LDX" and "lisdexamfetamine" to refer to L-lysine-d-amphetamine.

317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations .

. . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

DISCUSSION

I. Anticipation of claims 1, 2, and 5 of U.S. Patent No. 7,662,787

Defendants moved for partial summary judgment on anticipation of claims 1, 2, and 5 of U.S. Patent No. 7,662,787. Subsequently, the parties stipulated to the dismissal of the claims in the Amended Complaint dealing with these three patent claims, which were dismissed with prejudice. Plaintiffs oppose this motion on the ground that the Court now lacks subject matter jurisdiction to hear this motion. Plaintiffs are correct, as the Federal Circuit has stated:

> Article III, § 2 of the Constitution confines federal courts to the decision of "cases" or "controversies." Standing to sue or defend is an aspect of the case-or-controversy requirement. *Ne. Fla. Chapter, Associated Gen. Contractors of Am. v. Jacksonville*, 508 U.S. 656, 663-64, 113 S. Ct. 2297, 124 L. Ed. 2d 586 (1993). In the absence of Article III standing, a court lacks jurisdiction. *See*

> *Whitmore v. Arkansas*, 495 U.S. 149, 154-55, 110 S. Ct. 1717, 109 L. Ed. 2d 135 (1990) ("Article III, of course, gives the federal courts jurisdiction only over 'cases and controversies,' and the doctrine of standing serves to identify those disputes which are appropriately resolved through the judicial process.")

Samsung Elecs. Co. v. Rambus, Inc., 523 F.3d 1374, 1378 (Fed. Cir. 2008). Since the claims at issue in this motion have been dismissed, the motion raises no justiciable case or controversy, and the Court lacks jurisdiction to hear it. The motion will be denied for lack of subject matter jurisdiction.

II. Noninfringement

Defendants move for partial summary judgment of noninfringement as to two theories: 1) no direct infringement in regard to certain treatment method claims; and 2) no induced infringement of certain treatment method claims. As to the first theory, Plaintiffs oppose on the ground that the Amended Complaint asserts no claims of direct infringement of any method claim in a patent at issue. In reply, Defendants disagree and contend that the Amended Complaint does assert claims of direct infringement of method claims. This Court finds that, to the extent that the Amended Complaint asserts claims of direct infringement of method claims in the patents at issue, such claims have been abandoned, and they are dismissed with prejudice. As to the issue of direct infringement, the method claims at issue are:

1. Claims 1-4 and 6-15 of U.S. Patent No. 7,105,486;
2. Claim 13 of U.S. Patent No. 7,659,253;
3. Claims 1-8 of U.S. Patent No. 7,659,254;
4. Claims 1-7, 9-23, and 25-32 of U.S. Patent No. 7,671,031;
5. Claims 1-27 of U.S. Patent No. 7,678,770;
6. Claims 8-19, 21-23, 26-28, 30-35, 37-42, and 44-47 of U.S. Patent No. 7,662,788;
7. Claims 1-7, 9-23, 25-39, 41-55, and 57-67 of U.S. Patent No. 7,713,936;
8. Claim 43 of U.S. Patent No. 7,671,030; claim 43 of U.S. Patent No. 7,674,774; claim 43 of U.S. Patent No. 7,687,467; claim 43 of U.S. Patent

> No. 7,723,305; claim 43 of U.S. Patent No. 7,718,619; and claim 22 of U.S. Patent No. 7,678,771.

All claims of direct infringement of these method claims are dismissed with prejudice. This leaves the issue of inducement of infringement.

As to the issue of inducement of infringement, the ANDA Defendants move for partial summary judgment on three theories, contending that there is no evidence that the ANDA Defendants' proposed product labels induce infringement of method claims: 1) requiring administration with food; 2) requiring use of various rating scales; and 3) directed toward abuse resistance. Because the burden of proof of induced infringement is on Plaintiffs, Defendants meet their initial summary judgment burden by pointing to the absence of evidence to support these claims. The burden then shifts to Plaintiffs to point to evidence which raises a material factual dispute.[2]

As to the issue of inducing infringement of the rating scale claims, Plaintiffs contend that the proposed label induces infringement of claims 19-24 of the '770 patent. These claims all depend on claim 13, which states:

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[2] In the opposition and reply briefs, the parties debate the application of Bayer Schering Pharma AG & Bayer HealthCare Pharms., Inc. v. Lupin, Ltd., 676 F.3d 1316 (Fed. Cir. 2012). This Court need not reach questions of the meaning of Bayer which, in brief, applied the decision in Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1354-1355 (Fed. Cir. 2003):

> [I]t is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.

The decision on the present motion does not turn on, nor even concern, the issue of whether the ANDA seeks to market the drug for an FDA-approved or unapproved use. Rather, the decision turns on the straightforward question of whether the proposed label evidences an intent to induce infringement.

> A method of treating symptoms of attention deficit hyperactivity disorder in a subject six to twelve years of age in need thereof, said method comprising orally administering to said subject a pharmaceutically effective amount of L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof; whereby one or more of said symptoms diminish in said subject in a statistically significant amount as compared to a subject not receiving treatment of symptoms of attention deficit hyperactivity disorder.

'770 patent, col.73 ll.14-22. Claim 19 is a good exemplar of a claim which incorporates use of a rating system: "A method as defined in claim 13, wherein said diminishment is measured using the ADHD ratings scale." Id. at col.74 ll.5-6. As evidence which raises a factual dispute, Plaintiffs point to the two clinical study references on the proposed label which state that rating scales were used in the study. Plaintiffs do not explain, however, how this might induce anyone to do anything, much less encourage the infringing use of a rating scale in the treatment of ADHD. Nor does this Court perceive how any reasonable jury could hear this evidence and conclude that Defendants intended to encourage infringing use of a rating scale to measure diminishment of ADHD symptoms. The evidence that the label reports that researchers in the past did studies in which they measured diminishment of symptoms by using certain rating scales would not be sufficient to persuade a reasonable jury that Defendants intended to induce anyone to measure diminishment of symptoms by using these rating scales. Plaintiffs confuse the matter when they argue that the key question is whether the label instructs that use of lisdexamfetamine for treatment of ADHD "will *result in* diminished symptoms of ADHD according to the recited rating scales." (Pls.' Opp. Br. 15.) No, the central question here is whether the label instructs people to use rating scales to measure the diminishment of symptoms when using lisdexamfetamine dimesylate to treat ADHD.

Plaintiffs' attempt to raise a factual dispute fails. Plaintiffs' statement of additional

material facts does no more than point to the fact that the proposed label cites research studies in which ratings scales were used to measure diminishment of symptoms. Plaintiffs point to nothing in the label which instructs patients or physicians to perform any method used in a cited research study. Surprisingly, Plaintiffs point to testimony from their expert, Dr. McGough, in which he states that nothing requires the physician to administer a rating scale; rather, *if* one were to administer a rating scale, one would see evidence of diminishment of sumptoms. (Pls.' Opp. 56.1 Stmt. ¶ 48, citing McGough Ex. C, McGough Tr. 213:6-214:4). Plaintiffs next point to a number of sources of medical information that recommend the use of rating scales, which says nothing about the instructions on the proposed label. (Id. at ¶¶ 50-53.) Plaintiffs have failed to point to any evidence from which a reasonable jury could conclude that Defendants intended to induce anyone to measure diminishment of ADHD symptoms by using rating scales.

As to the issue of inducing infringement of claims with limitations involving administration with food, Plaintiffs contend that the proposed label induces infringement of claims 2-8 of the '254 patent. Claims 3-8 depend on claim 2, which states:

> 2. A method of treating an adult subject having attention deficit hyperactivity disorder, said method comprising orally administering to said subject a pharmaceutically effective amount of L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof with intake of food by said subject.

As evidence which raises a factual dispute, Plaintiffs point to the proposed label statement, under the heading "Dosage and Administration," that the products may be taken "with or without food." (Pls.' Opp. 56.1 Stmt. ¶ 16.) This is not sufficient to raise a factual dispute as to whether Defendants intended to induce anyone to infringe by taking the medication with food. "Evidence of active steps . . . taken to encourage direct infringement, such as advertising an infringing use

or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." MGM Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (citation omitted). The problem is that the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement. Plaintiffs point to the statements of their expert, Dr. McGough, but none of his conclusory assertions get around the simple fact that the proposed label does not contain any instruction to take the medication with food. Plaintiffs have failed to raise a material factual dispute over whether the proposed label encourages infringement of method claims requiring administration with food.

As to the issue of inducing infringement of claims directed toward reduced abuse potential, Plaintiffs contend that the proposed label induces infringement of claims 1-6, 8-23, 25-28, 30-35, 37-42, and 44-47 of the '788 patent. These claims all depend on independent claim 1, which states:

> A method of decreasing abuse of amphetamines or salts thereof, in a subject in need thereof, said method comprising supplying said amphetamine to said subject in the form of L-lysine-d-amphetamine or a salt thereof.

'788 patent, col.68 ll.40-43. Plaintiffs argue that the proposed label encourages infringement of these claims by citing clinical research studies that support an inference of decreased abuse potential. Defendants argue that, even if the patented method is construed as a method for decreasing amphetamine abuse, they cannot induce infringement where, as here, the use in question has not been approved by the FDA, pursuant to Bayer Schering Pharma AG & Bayer HealthCare Pharms., Inc. v. Lupin, Ltd., 676 F.3d 1316, 1321 (Fed. Cir. 2012).

The parties do not dispute the relevant legal principle, that an ANDA applicant cannot induce infringement of a method patent unless that method has been approved by the FDA. Id. Rather, the focus of the dispute is whether "decreasing amphetamine abuse" is an FDA-approved use. Plaintiffs' arguments in their opposition brief rely on circumlocutions which obscure the fact that Plaintiffs do not assert that "decreasing amphetamine abuse," in and of itself, is an FDA-approved use for lisdexamfetamine dimesylate, nor do they point to any evidence sufficient to persuade a reasonable jury that the FDA has approved that use. Typical of these circumlocutions is this statement: "The ANDA Defendants' product labeling contains information, in the form of human abuse liability studies, on the safety and efficacy of the use of the drug to decrease amphetamine abuse while treating ADHD, which indicates that this use is FDA approved." (Pls.' Opp. Br. 25.) This statement attempts to obscure the fact that Plaintiffs have no evidence that the FDA has approved lisdexamfetamine dimesylate as a treatment for amphetamine abuse. The simple truth is that the proposed labels state: "Lisdexamfetamine Dimesylate Capsules are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)." (See, e.g., Fleming Dec. Ex. 8 at ROXLDX055824.) The labels do not say that the products are indicated for the treatment of amphetamine abuse. Because there is no evidence that the FDA has approved the use of lisdexamfetamine dimesylate as a treatment for amphetamine abuse, Defendants' product label cannot induce infringement of a method patent.

Furthermore, the decreased abuse potential appears to be a characteristic of the method, not an element of the method itself. Decreased abuse potential is neither a composition nor a method step. It is not an operative step that can be encouraged or not encouraged. Rather, it is an attribute of the method which states an abstract effect, the decrease in risk of a particular bad

outcome, amphetamine abuse. This Court is not persuaded that Plaintiffs have adequately alleged inducement of an infringing method step.

Lastly, the language at issue in claim 1 appears to be a preamble rather than a claim limitation. When a party asserts that preamble language should be understood to state a claim limitation, under Federal Circuit precedent, the Court must perform a careful inquiry into the question. "[A] preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" Braintree Labs., Inc. v. Novel Labs., Inc., 2014 U.S. App. LEXIS 7495, *15-*16 (Fed. Cir. Apr. 22, 2014) (quoting Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997)). The patentee appears to have used the claim language relating to decreasing abuse of amphetamines only to state a purpose for the invention. The body of the claim defines a structurally complete invention. There is no basis to find that the preamble serves as a claim limitation. If the preamble is not a claim limitation, it cannot be used to assert liability for infringement or for inducing infringement.

Plaintiffs have failed to raise any genuine factual disputes which might preclude the entry of judgment as a matter of law. As to the claims for inducing infringement of claims 2-8 of the '254 patent, claims 19-24 of the '770 patent, and claims 1-6, 8-23, 25-28, 30-35, 37-42, and 44-47 of the '788 patent, Plaintiffs have failed to defeat the ANDA Defendants' motion for partial summary judgment of noninfringement, and judgment on these claims will be entered in the ANDA Defendants' favor. Any claims in the Amended Complaint for direct infringement of method claims have been abandoned and will be dismissed with prejudice.

III. Invalidity under 35 U.S.C. § 101

Defendants move for partial summary judgment of invalidity on almost 250 claims in six patents on the ground that the subject matter is unpatentable laws of nature, relying principally on Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012). Defendants' brief uses the claims in the '030 patent as exemplars. As Defendants state, generally speaking, the claims of the '030 patent require a composition comprising a specified amount of lisdexamfetamine or a salt thereof, and requirements as to various specified pharmacokinetic properties of the lisdexamfetamine.

Defendants' argument, in brief, is that, as to these patents, this case is on all fours with Mayo. This argument, however, fails because of the distinction that Mayo involved a method patent and the patents at issue on this motion are composition patents. Thus, in Mayo, the Supreme Court held:

> If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law."

132 S. Ct. at 1297. The claims at issue on this motion are not process claims. The claims are directed to a composition. Defendants make no persuasive argument that these claims are directed to a process which attempts to monopolize the laws of nature.

The Federal Circuit addressed a similar argument in Ass'n for Molecular Pathology v. United States PTO, 689 F.3d 1303, 1325 (Fed. Cir. 2012), rev'd on other grounds, 133 S. Ct. 2107 (2013), where appellant argued that "that the Supreme Court's decision [in *Mayo*] did not address or alter the established patent-eligibility test for composition claims, such that the

standards announced in *Chakrabarty* still govern [that issue]." The Federal Circuit agreed:

> While *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter.

Id. at 1326. Mayo does not alter the patent-eligibility test for composition claims.

This is clear from the text of Mayo as well. In Mayo, the Supreme Court read the patent claims and found that they:

> set forth laws of nature – namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. . . While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body-entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

Id. at 1296-97. The Supreme Court then articulated the inquiry as follows:

> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that apply natural laws?

Id. at 1297.

Applying Mayo to the instant case, then, this Court asks whether the claims at issue describe processes. As already discussed, the claims at issue are directed to the compound, lisdexamfetamine. From the outset, then, this Court wonders how lisdexamfetamine might be considered a process that applies a law of nature, such that Mayo is relevant?

Defendants avoid this issue by pointing to the pharmacokinetic properties limitations in the claims: "Shire's claims include limitations that involve nothing more than recording the

results of how a body naturally acts upon the drug or the presence of the drug in the body acts upon the body." (Defs.' Br. 12.) Even if this Court accepted this argument – which it does not –, it would not suffice to show that the claims are directed to a process that applies a law of nature. Defendants have failed to persuade the Court that these claims are directed to ineligible subject matter under Mayo. Defendants' motion for partial summary judgment will be denied.

IV. No willful infringement

Defendants have moved for partial summary judgment on any claim of willful infringement, contending that Plaintiffs have no evidence to support such a finding. Because Plaintiffs bear the burden of proof of willful infringement, the summary judgment burden shifts to them. Plaintiffs have failed to clearly articulate a basis for this Court to make a finding of willful infringement, much less offered sufficient evidence.

It is not clear from Plaintiffs' opposition brief whether they allege willful infringement on the part of only JM, or all Defendants, but Plaintiffs do not persuade that they could succeed on such a claim against any Defendant. Plaintiffs seek damages for willful infringement pursuant to 35 U.S.C. § 285, which states: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." This motion turns on whether Plaintiffs have offered a basis for this Court to find that this is an exceptional case.

The Supreme Court recently stated the law of § 285 as follows:

> We hold, then, that an "exceptional" case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances.

Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1756 (2014). Quite simply, Plaintiffs have made no showing that this qualifies as an exceptional infringement case. To the contrary, the record indicates that it is, on the whole, a fairly typical Hatch-Waxman case. JM and the ANDA Defendants are alleged to have done the kinds of things Defendants in these cases typically do when they seek to market a generic version of a pharmaceutical protected by patents. This case does not stand out from others either in terms of the substantive strength of Plaintiffs' case, or in the manner in which any Defendant has litigated it.

A useful point of comparison, even though it preceded the Octane decision, is the Federal Circuit's decision in Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000). The Federal Circuit affirmed the district court's finding of willful infringement and the award under § 285, holding that "Danbury's misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed warranted the district court's finding that this case was exceptional." Id. Plaintiffs have not pointed to anything in the instant case that rises to that level. What is the misconduct here?

As already stated, the conduct of the ANDA Defendants alleged by Plaintiffs appears to be the typical conduct of ANDA applicants. As to JM, the record shows, at most, that JM was, as Plaintiffs contend, a "prime mover" in the sequence of events leading to the filing of ANDAs by the ANDA Defendants. Such conduct ordinarily falls within the protection of the "safe harbor" provision, 35 U.S.C. § 271(e)(1), which states:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The Supreme Court has made the broad scope of this provision clear:

> [W]e think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.

Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005). Plaintiffs attempt to make the case that JM's conduct here extends beyond the scope of § 271(e)(1) because, allegedly, JM and the ANDA Defendants have signed supply contracts in which JM has offered to sell in the future a compound presently protected by patents. This Court is not persuaded that such conduct – where the potentially infringing activity is contingent on the occurrence of two remote events, the FDA's approval of the ANDA, and the generic product's entry into the marketplace – is not, to this point, reasonably related to the ANDA process.

This Court sees no basis for it to exercise its discretion to award attorneys' fees pursuant to 35 U.S.C. § 285. Rather, an award of fees in this case would run contrary to the policies on which the Hatch-Waxman Act is based. As the Federal Circuit has explained:

> [W]e now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4). The Supreme Court has emphasized that 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(e)(4) create an "artificial" act of infringement only for a "very limited and technical purpose that relates only to certain drug applications." *Eli Lilly*, 110 L. Ed. 2d at 623. This purpose, as the Supreme Court explains, is to permit patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue. *Eli Lilly*, 110 L. Ed. 2d at 624. In evaluating 35 U.S.C. § 271(e)(2), we have in our past decisions considered this provision to be primarily a jurisdictional-conferring statute that establishes a case or controversy in a declaratory judgment action. The district court therefore erred in hanging a finding of willfulness on such a special-purpose peg.

Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350-1351 (Fed. Cir. 2004) (citations omitted).

Under Glaxo, Plaintiffs here cannot show that the ANDA Defendants willfully infringed Plaintiffs' patents merely by filing ANDAs. Yet Plaintiffs argue that JM, because it is a third party which did not file an ANDA, should be penalized for conduct that is, essentially, related to the ANDA submission process. Plaintiffs have not shown any good reason why JM, as a manufacturer agreeing to supply an ANDA filer, should be penalized for conduct which a manufacturer/ANDA filer is permitted under Glaxo.

Plaintiffs have not produced evidence sufficient to persuade this Court to exercise its discretion under § 285 to find that this is an exceptional case. Defendants' motion for partial summary judgment of no willful infringement will be granted.

V. No indirect infringement

This motion is brought by Defendants Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials (collectively, "JM") and seeks partial summary judgment of no indirect infringement, that is, no infringement under induced and contributory infringement theories. As an initial matter, it is true, as Shire suggests, that JM's opening brief is confusing as to the subject of exactly which claims in which patents are at issue on this motion. In its reply brief, JM states that the parties have stipulated to the dismissal of a group of claims, leaving 125 claims. JM divides this group of claims into the "addressed" claims (those addressed by expert McGough) and the "unaddressed" claims, as detailed in the reply brief Exhibit A. JM argues that Plaintiffs have no evidence of indirect infringement of these claims. Because the burden of proof of infringement is on Plaintiffs, JM has met its initial summary judgment burden, and the burden then shifts to Plaintiffs to point to sufficient evidence to support a jury verdict in Plaintiffs' favor.

"To prove inducement, the patentee must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010) (citation omitted). As to JM's knowledge of the patents, Plaintiffs point to evidence that JM employees knew about the Vyvanse® patents listed in the Orange Book. (Pls.' Rule 56.1 Stmt. ¶¶ 49, 57, 58, 62.) As to JM's specific intent to encourage another's infringement, Plaintiffs point to the undisputed fact that JM provided a drug master file ("DMF") supporting Defendants' ANDA applications. If Plaintiffs are able to prove that there was direct infringement by a Defendant, this evidence could persuade a reasonable jury that JM induced infringement. As Plaintiffs contend, this evidence is sufficient to raise a factual dispute for trial. Because JM's motion was based on the contention that Plaintiffs have no evidence, pointing to this evidence is sufficient to defeat the motion for partial summary judgment.

In the reply brief, JM raises new arguments about Federal Circuit law, including the argument that inducing filing of an ANDA cannot create liability. Although this Court need not reach this argument to decide this motion, this Court rejects JM's reading of Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1272 (Fed. Cir. 2007) (citations omitted), which states:

> Section 271(e)(2) may support an action for induced infringement. The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered. An inquiry into induced infringement focuses on the party accused of inducement as the prime mover in the chain of events leading to infringement. Here, we do not know if Cipla first approached Ivax or vice versa, but the plan to manufacture, import, market, and sell the EO products described in the ANDA was undoubtedly a cooperative venture, and Cipla was to manufacture and sell infringing EO products to Ivax for resale in the United States. Under the standards for inducement which we apply to 35 U.S.C. § 271(b), Cipla has therefore actively induced the acts of Ivax that will constitute

> direct infringement upon approval of the ANDA, and it was thus not inappropriate for the district court to include Cipla within the scope of the injunction.

It appears to this Court that Forest speaks clearly to the question of whether inducing the filing of an ANDA can create inducement liability for an ANDA applicant's manufacturer/supplier. JM's argument that Forest may be distinguished because of a stipulation to infringement is irrelevant. Contrary to JM's position, this Court understands Forest to stand for the proposition that Plantiffs' theory of JM's liability for inducing infringement is legally viable.

JM's motion for partial summary judgment of no indirect infringement will be denied.

VI. Infringement and invalidity of four patents

Plaintiffs have moved for summary judgment that claims in four patents are infringed and not invalid. The motion concerns these claims: 1) compound claims 1-4 of U.S. Patent No. 7,655,630 (the "'630 patent"); 2) compound claim 3 of U.S. Patent No. 7,662,787 (the "'787 patent"); 3) compound claims 1-12 of U.S. Patent No. 7,659,253 (the "'253 patent"); and 4) method claim 4 of U.S. Patent No. 7,105,486 (the "'486 patent"). Plaintiffs contend that the ANDA Defendants directly infringe the compound claims and induce infringement of the method claim. Plaintiffs also contend that JM both directly infringes and induces infringement of the compound claims.

A. Infringement

As to the ANDA Defendants' direct infringement of the compound claims, these claims are directed to the compound lisdexamfetamine dismesylate, and there is no dispute that Defendants' ANDAs seek to market pharmaceuticals with lisdexamfetamine dismesylate as the active ingredient. (Defs.' 56.1. Stmt. ¶¶ 78-83.) As to the compound claims, Defendants oppose

the motion for summary judgment solely on the basis that these claims are not infringed because they are invalid. Defendants have raised no material factual disputes related to direct infringement of the compound claims and, setting invalidity aside for the moment, as to the issue of direct infringement of the compound claims, the motion for summary judgment will be granted. There is no real dispute about the ANDA Defendants' direct infringement of the compound claims.

As to the question of whether the ANDA Defendants' proposed product labels induce infringement of method claim 4 of the '486 patent, Federal Circuit law requires that patentee to prove the following elements:

> In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.

3M v. Chemque, Inc., 303 F.3d 1294, 1304-1305 (Fed. Cir. 2002). The holder of a method patent may sue an ANDA filer for induced infringement under § 271(e)(2) if the ANDA applicant seeks FDA approval for the use claimed in the patent and if the use claimed in the patent is FDA-approved. Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1332 (Fed. Cir. 2003). There is no dispute here that the ANDA Defendants seek FDA approval for the use claimed in the '486 patent, nor that such use is FDA-approved. Nor is there any dispute that the ANDA Defendants knew about the '486 patent, since each filed paragraph IV certifications against this patent, which was listed in the Orange Book as covering Vyvanse®. As to the element of specific intent, the Federal Circuit has held:

> The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [the ANDA

applicant's] affirmative intent to induce infringement.

AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010). Plaintiffs thus point to the proposed labels for the generic products as evidence of the ANDA Defendants' affirmative intent to induce infringement.

Plaintiffs have thus pointed to evidence sufficient to allow a reasonable jury to determine that a case for induced infringement of the method patent has been made. The burden then shifts to Defendants to raise a material factual dispute. Defendants' opposition brief does not address this issue. The motion for summary judgment that the ANDA Defendants have induced infringement of claim 4 of the '486 patent will be granted.

To the extent that Plaintiffs move for summary judgment that JM directly infringes the compound claims, the motion will be denied, since JM's manufacture of lisdexamfetamine dismesylate falls within the safe harbor provision of 35 U.S.C. § 271(e)(1), which exempts activities reasonably related to the submission of an ANDA. Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1354 (Fed. Cir. 2012).

Lastly, as to whether JM is liable for inducing the ANDA Defendants' direct infringement of the compound claims, Plaintiffs point to the undisputed facts that the ANDAs at issue list JM as the manufacturer of the lisdexamfetamine dismesylate used in the generic products, and that JM has provided Drug Master File ("DMF") No. 22442 to the FDA. (Defs.' 56.1. Stmt. ¶¶ 33, 34.) In opposition, Defendants argue that the motion should be denied because Plaintiffs have failed to "address the specific intent or knowledge of infringement elements of the induced-infringement analysis." (Defs.' Opp. Br. 26.) This misapprehends the requirements of Rule 56. Plaintiffs, who bear the burden of proof of induced infringement, have offered evidence

from which a reasonable jury could find that the elements of induced infringement have been proven. The burden then shifts to Defendants to point to evidence of record which raises a genuine material factual dispute. Defendants have not done so, and have failed to defeat Plaintiffs' motion for summary judgment that JM is liable for inducing the ANDA Defendants' direct infringement of the compound claims.

B. Invalidity

Plaintiffs move for summary judgment that the claims at issue are not invalid, contending that Defendants have failed to offer proof that the claims are invalid due to anticipation or obviousness. This Court heard oral argument on these issues on April 29, 2014, and ordered supplemental briefing on the issue of invalidity due to obviousness.

"A patent is presumed to be valid, 35 U.S.C. § 282, and this presumption can only be overcome by clear and convincing evidence to the contrary." Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001) (citations omitted). The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. "This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (quotation omitted).

Because Defendants bear the burden of proof of invalidity, Plaintiffs meet their initial burden by pointing to the absence of evidence to support Defendants' invalidity case, and the summary judgment burden then shifts to Defendants.

As to anticipation, Defendants contend that the compound patents at issue are anticipated by Australian Patent Application No. AU 54,168/65 ("AU '168.") "A patent claim is anticipated

if each and every limitation is found in a single prior art reference." Osram Sylvania, Inc. v. Am. Induction Techs., Inc., 701 F.3d 698, 704 (Fed. Cir. 2012). "Anticipation is a question of fact. . . Summary judgment is proper if no reasonable jury could find that the patent is not anticipated." Zenith Elecs. Corp. v. PDI Commun. Sys., 522 F.3d 1348, 1356-57 (Fed. Cir. 2008).

There is no dispute that AU '168 does not expressly disclose the compound lisdexamfetamine dismesylate. Rather, Defendants rely on the following language:

> α-Amino acid amides which contain free α-amino groups form non-toxic acid addition salts with pharmaceutically acceptable inorganic and organic acids. Thus, they form pharmaceutically acceptable acid addition salts with medicinally acceptable acids such as hydrochloric acid, sulphuric acid, oxalic acid, acetic acid, phosphoric acid, p-toluene sulphonic acid, sulphosalicylic acid, β-naphthoic acid, citric acid, benzoic acid, sorbic acid and the like.

(Ragosa Dec. Ex. 3 at VYVANSE_JDG_00001816.) Defendants contend that the phrase "and the like," as used here, states "a limited class of 20 or fewer acids, including methanesulfonic acid." (Defs.' Opp. Br. 10.) Defendants argue that this states a genus which anticipates a species within that genus, lisdexamfetamine dismesylate.

The Federal Circuit has held:

> It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. *See, e.g., In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus. On the other hand, a very small genus can be a disclosure of each species within the genus.

Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999 (Fed. Cir. 2006). The parties do not dispute that the relevant legal test used to determine whether a genus anticipates a species asks whether the prior art "expressly spelled out a definite and limited class of compounds that enabled a person of ordinary skill in the art to at once envisage each member of this limited

class." Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1376 (Fed. Cir. 2006).

Defendants have failed to persuade this Court that the AU '168 reference has "expressly spelled out a definite and limited class of compounds." Rather, there is simply no way that "and the like" can be said to expressly spell out a definite class of anything. No reasonable jury could ever conclude otherwise.

Defendants argue that the dispute over the meaning of "and the like" involves a "classic battle of the experts." (Defs.' Opp. Br. 10.) This dispute does not, however, raise a material factual dispute sufficient to defeat the motion for summary judgment. While the experts may disagree about the meaning of the phrase "and the like" in AU '168, no reasonable jury could ever conclude from the evidence of record that this phrase expressly spells out a definite and limited class of compounds. Furthermore, the Court need not credit conclusory statements by experts and need not find such statements sufficient to raise material factual disputes. Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1365 (Fed. Cir. 2007) ("We have repeatedly held that such cursory conclusions will not withstand summary judgment.") Defendants' expert, Dr. Atwood, did not even make the conclusory statement that "and the like" expressly spells out a definite and limited class of compounds in his expert reports or deposition testimony. Rather, his opinion does not go further than to say that the skilled artisan would understand "and the like" to include methanesulfonic acid. Paragraphs 55-58 in Defendants' Supplemental Rule 56.1 Statement deal with Atwood's opinion on this subject. In paragraph 66 of his expert report, Atwood said only that "a POSA would immediately envision that 'the like' in Hellerbach includes methanesulfonic acid." (Atwood Dec. Ex. A ¶ 66.) In the deposition testimony cited in paragraphs 55-58 in Defendants' Supplemental Rule 56.1 Statement, Atwood does not say much

more, and he does not assert that "and the like" expressly spells out a definite and limited class of compounds.[3] It is only in the declaration that accompanies the expert reports that Atwood makes the purely conclusory assertion that AU '168 "discloses a definite and limited class of medicinally acceptable acids." (Atwood Dec. ¶ 17.) Under Stumbo, this is insufficient to defeat a motion for summary judgment.

Defendants' brief also incorporates by reference the anticipation arguments made in Defendants' separate motion for partial summary judgment of claims 1, 2, and 5 of the '787 patent. The one different argument that appears in that motion, and which also appears in Defendants' supplemental brief for the instant motion, is based on the Federal Circuit's decision in Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC, 683 F.3d 1356, 1361 (Fed. Cir. 2012). Defendants contend that Wrigley stands for the proposition that "multiple disclosures within the same reference may be combined to form an anticipatory disclosure if they are directly related."[4]

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[3] Rather, in the deposition testimony cited by Defendants, Atwood merely says that the list of pharmaceutically acceptable organic acids encompassed by the "and the like" phrase is "20 or less." (Atwood Dec. Ex. C 162:21.) In Atwood's Reply Report, however, he stated a different number:

> 22. [. . .] As shown in Berge and Gould, the FDA has approved approximately 50 different salts forms [sic] of various molecules, including mesylate. . .
> 23. Therefore, when reading Hellerbach, a POSA would have immediately envisaged at least those salt forms . . .

(Atwood Dec. Ex. B.) At oral argument, the Court inquired about the apparent inconsistency in Atwood's statements, and Defendants' counsel contended that an unspecified "final modifier" would reduce the number from 50 to 20. (Hearing Tr. 39:17-40:7.) The Court does not rely on this potential inconsistency in arriving at its decision here. Rather, the essential finding is that Atwood did not support his conclusory assertion that AU '168 "discloses a definite and limited class of medicinally acceptable acids."

[4] This sounds nice, but, in short, Wrigley does not stand for that proposition. In Wrigley, the Federal Circuit did not create a whole new kind of piecemeal anticipation which uses a

(Defs.' Supp. Br. 6.) On this basis, Defendants contend that Wrigley supports their attempt to find lisdexamfetamine disclosed in AU '168.

In the supplemental brief, in short, Defendants make two arguments. The first is: 1) AU '168 discloses protected lisdexamphetamine in Example 24; 2) AU '168 discloses how to deprotect protected compounds; therefore 3) applying Wrigley, you combine these disclosures to find anticipatory disclosure of unprotected lisdexamfetamine. The second argument, also made in the brief for summary judgment on the '787 patent, is similar, but with one major difference. In this argument, Defendants do not begin with the protected lisdexamphetamine in Example 24, but with the components: AU '168 has two lists, one with L-lysine on it, one with d-amphetamine on it, and it teaches how to couple them to make protected lisdexamfetamine. Then it teaches deprotection of this intermediate.

This Court rejects these arguments that application of Wrigley allows Defendants to find lisdexamfetamine disclosed in AU '168.[5] In Wrigley, the prior art reference contained two lists, and the claim at issue combined one element from each list to make a chewing gum formula. Id. The Federal Circuit stated the crux of the anticipation issue as follows: "The question for purposes of anticipation is therefore whether the number of categories and components in [the single prior art reference] was so large that the combination of WS-23 and menthol would not be immediately apparent to one of ordinary skill in the art." Id. Defendants do not mention this in

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"directly related" test.

[5] Defendants also make the curious argument that the Court should "presume" that lisdexamfetamine is disclosed in AU '168. Defendants have not persuaded this Court that they are entitled to such a presumption, nor that such a presumption would benefit them in the anticipation inquiry.

their discussions of Wrigley, and it is a crucial omission.

Defendants contend that the instant case is like Wrigley, but have failed to persuade this Court. The instant case is not analogous to Wrigley, for several reasons. First, it is just not true that AU '168 has two lists, one with L-lysine on it and one with d-amphetamine on it. At best, AU '168 discloses amphetamine, a preference for d-amphetamine, a list of 18 amino acids which includes lysine, and a preference for the L forms of the amino acids. Second, not that this Court has any expertise with the production of chewing gum, but lisdexamfetamine does not appear to be something that you get just by mixing a little L-lysine and a little d-amphetamine together. There is no dispute that some chemical reactions have to take place, including synthesizing a protected intermediate and then performing a reaction which deprotects that intermediate. Finally, the compound at issue on this motion is not lisdexamfetamine, but lisdexamfetamine dimesylate. And the acid that is used to form the dimesylate salt does not appear on any list in AU '168. No amount of list-picking from AU '168 can end up with lisdexamfetamine dimesylate.

Much of this critique also holds true for Defendants' argument that begins with Example 24 in AU '168. Combining formula ingredients picked from two separate lists (as in Wrigley) is not analogous to "combining" a compound (protected lidsexamfetamine) with a technique (deprotection). The fact that the English language allows us to use the word "combining" in both contexts does not demonstrate that the phrases have the same meaning. Combining two ingredients is not the same as combining an ingredient and a technique. And, again, setting this objection aside, this argument does not have as its end product the compound at issue, lisdexamfetamine dimesylate.

Defendants have failed to point to evidence sufficient to persuade a reasonable jury that AU '168 anticipates by disclosing lisdexamfetamine dismesylate. Plaintiffs' motion for summary judgment of no anticipation will be granted.

Plaintiffs also move for summary judgment of no invalidity of any patent at issue due to obviousness. Again, because Defendants bear the burden of proof of invalidity, Plaintiffs meet their initial burden by pointing to the absence of evidence to support Defendants' invalidity case, and the summary judgment burden then shifts to Defendants.

The relevant statutory provision states:

> A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

35 U.S.C. § 103. The parties dispute, however, what approach this Court should take to the obviousness inquiry. Plaintiffs contend that this Court should apply the "lead compound" obviousness inquiry used by the Federal Circuit in Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280, 1291-92 (Fed. Cir. 2012). Defendants assert that a finding of non-obviousness "rests on two underlying factual issues: rationales for modification and reasonable expectation of success." (Defs.' Opp. Br. 14.)

In their supplemental brief, Defendants clarify their objections to the "lead compound" inquiry: 1) "courts do not apply the lead compound analysis to claims directed to new salts of active drug substances anticipated by the prior art" (Defs.' Supp. Br. 9); and 2) "lead compound analysis does not apply to pharmaceutical salts of known actives because salt formation does not modify the underlying chemical structure of the parent compound." (Id. at 10.)

Defendants' approach to the obviousness inquiry is problematic from the start. The first objection contains a puzzling formulation: "new salts of active drug substances anticipated by the prior art." Doesn't "anticipated by the prior art" have the same meaning as "disclosed in the prior art"? Both objections appear to rely on the assumption that there exists an active drug compound in the prior art, and that the only difference between the prior art and the claimed invention is that the claimed invention is a new salt form of the prior art compound. Crucially, Defendants have not offered the prior art reference that discloses lisdexamfetamine. This Court need not reach the legal question of whether Defendants may be excused from satisfying the requirements of the lead compound analysis, since they have failed to establish the key assumption on which their argument depends.

This Court will, nonetheless, discuss the two cases on which Defendants rely: Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) and Valeant Int'l Berm. v. Actavis, Inc., 534 Fed. Appx. 999 (Fed. Cir. 2013). Defendants emphasize that neither of these cases even mentioned the "lead compound" analysis. At issue in Pfizer was the obviousness of compound claims directed to amlodipine besylate, "an acid addition salt form of amlodipine." Id. at 1353. A prior art patent expressly disclosed amlodipine and its acid addition salt forms, but not amlodipine besylate. Id. at 1361. Although the prior art patent did not expressly disclose amlodipine besylate, the Federal Circuit noted that the patent's "claims literally encompass amlodipine besylate." Id.

The first problem for Defendants is that the instant case is not analogous to Pfizer, where the active drug compound was not only disclosed in the prior art, and the claim at issue was for a compound that was a salt form of that active, but claims in a prior art patent were found to

literally encompass the compound at issue. None of these are true in the instant case. Pfizer is thus inapposite.

In Valeant, the Federal Circuit affirmed without opinion the district court's decision, Valeant Int'l (Barbados) SRL v. Watson Pharms., Inc., 2011 U.S. Dist. LEXIS 128742 (S.D. Fla. Nov. 7, 2011). The case concerned patents covering the pharmaceutical compound buproprion hydrobromide. (Id. at *3.) The district court found that the prior art disclosed both the active ingredient and various salt forms of it, but not the hydrobromide salt. (Id. at *4.) The district court limited the obviousness inquiry to the salt selection process, since the active was a known compound. (Id. at *19.) Again, the facts of Valeant are not analogous to the instant case, since Defendants have not shown that lisdexamfetamine or its salts were known in the prior art.

Defendants have failed to persuade this Court that the obviousness inquiry in this case should begin with the existence of lisdexamfetamine and look only at salt selection. Yet, even if Defendants had succeeded at showing that lisdexamfetamine was disclosed in AU '168, they still would not have a complete obviousness theory. Defendants have articulated a way that a skilled artisan might have picked and chosen from all the options in AU '168 to envisage lisdexamfetamine. That does not, however, equate to showing that lisdexamfetamine was a known active drug substance. Defendants have pointed to no evidence that the prior art knew of lisdexamfetamine as an active drug substance, nor evidence that the prior art had any knowledge of any of the characteristics of lisdexamfetamine. Thus, even if this Court had been persuaded that lisdexamfetamine was known as a compound, it has not been shown that it was known as a drug. Even if one were to begin with lisdexamfetamine as a known chemical entity, it would still be necessary to explain why the skilled artisan would have picked that chemical entity out of all

the others similarly disclosed in AU '168. And, then, why would the skilled artisan have been motivated to modify lisdexamfetamine to make lisdexamfetamine dimesylate?

Consider, by way of contrast, the facts of Pfizer and Valeant: in both cases, the active was previously known in the prior art as an active drug substance. These decisions did not mention the "lead compound" concept because there was no need for it; one does not need to explain why a known active drug substance would be a subject of investigation. In the instant case, there is no evidence that lisdexamfetamine was a known active drug substance, and a theory of obviousness must explain why a skilled artisan would have picked lisdexamfetamine out of all the compounds suggested in AU '168 and chosen a path of modification that would have produced lisdexamfetamine dimesylate.

Because Defendants have not shown that lisdexamfetamine was disclosed in the prior art, the obviousness analysis must begin at the beginning, before the active was known, which is what the "lead compound" analysis does. Such an analysis begins as follows:

> Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.

Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed. Cir. 2007). Defendants, as an alternative argument in case this Court did not agree with their position on the "lead compound" analysis, have proposed a "lead compound" theory. As articulated by Defendants' expert, Dr. Borch, the lead compound is d-amphetamine, which is disclosed in AU '168. (Defs.' Supp. Br. Ex. 5 ¶ 45.) Both amino acids and prodrugs were well-known, Borch stated, and AU '168 taught the synthesis of various amino acid/d-amphetamine prodrugs, stating

a preference for the L series of amino acids. (Id. at ¶ 49.) Borch observes that AU '168 discloses a mono-protected form of lisdexamfetamine, as well as a method for deprotecting it.

As to identifying the reason to modify d-amphetamine, Borch relies on this statement in AU '168:

> Amphetamine, as is well-known, exerts an appetite inhibiting effect as well as a high central nervous system stimulatory effect. Depending on the type of α-amino carboxylic acid used in the formation of the amides of formula I above, it is possible to improve the therapeutic range.

AU '168 at 16. Thus, what Borch is saying that AU '168 encouraged skilled artisans to try out different combinations of amphetamine and the 18 amino acids listed on page 7, with preferences for the D form of amphetamine and the L form of the amino acid. Neither Defendants' supplemental brief nor Dr. Borch's report gives any reason why the skilled artisan would have selected lysine. Thus, this is an "obvious to try" theory with a set of 18 possibilities.[6] Defendants do not propose a theory in which the skilled artisan has a reason to pick lysine from that group.

In KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007), the Supreme Court held that obviousness may be proven using an "obvious to try" theory when certain conditions are present:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Thus, in considering Defendants' evidence is support of its "obvious to try" theory, this Court

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[6] This is a key and fatal defect in Defendants' obviousness case: they have failed to recognize that their theory is an "obvious to try" theory, and to support it accordingly.

must inquire as to whether the theory could satisfy the KSR requirements. Defendants' theory cannot do so. Defendants have summarized their theory as follows:

> For similar reasons, it also would have been obvious to a POSA to try conjugating d-amphetamine to the L-series amino acids expressly named by AU '168 on page 7, including L-lysine. The benefits touted by the prior art represent design needs favoring such a combination. (Ex. 5, Borch Report at ¶¶68-72.) Further, the L-series amino acids named on page 7, but not employed in the experimental examples of AU '168, are part of a small and finite group expressly preferred by AU '168. (Id. at ¶¶77-78.)

(Defs.' Supp. Br. 12.) Defendants have not clearly articulated the design need or market pressure to solve a problem. At best, they point to a statement in AU '168 related to a search for appetite suppressants that are free from central nervous system stimulatory effects.[7] Yet, even if this is taken as the problem, Defendants have failed to explain why the 18 amino acids stated in AU '168 form a finite number of identified and predictable solutions to this problem. Defendants' argument appears to be limited to the assertion that the L forms of the 18 amino acids "are part of a small and finite group." (Defs.' Supp. Br. 12.) This argument, however, fails to address the requirements of being "predictable solutions" to a specific problem. How are the 18 amino acids predictable solutions? Defendants do not point to anything which supports the inference that these are solutions to a particular problem, and certainly not that they are predictable.

Defendants have failed to point to evidence which could establish every element of an "obvious to try" theory. Having failed to point to evidence sufficient to establish their obviousness theory, they have failed to defeat the motion for summary judgment regarding

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[7] They also cite two other references which teach that prodrugs "regulate the release of the active and reduce unwanted side effects" and may "lead to less euphoria and abuse potential." (Defs.' Supp. Br. 11.) Even if these statements of the possible benefits of prodrugs are taken as statements of design need, how do they point to the set of 18 amino acids, limited to the L form, disclosed in AU '168, as predictable solutions? They don't.

invalidity due to obviousness of the compound patents.

Plaintiffs contend that there is a complete failure of proof of invalidity of method claim 4 of the '486 patent. In their opposition brief, Defendants presented their case for invalidity due to obviousness of this claim, which is directed to a method of treatment for ADHD using a mesylate salt of lisdexamfetamine. The brief points to the evidence in Defendants' Supplemental Rule 56.1 Statement paragraphs 88-90. In short, all Defendants have offered are the conclusory opinions of two experts, Feifel and Atwood. The reference to Atwood's expert opinion is misleading at best. Defendants point to Atwood's expert report, which does indeed state that he considered claim 4 of the '486 patent. (Atwood Dec. Ex. A. ¶ 34.) Atwood, however, is Defendants' expert on salt selection. Defendants did not retain Atwood to opine on methods of treatment for ADHD, and Atwood's expert report does not address methods of treatment for ADHD.

As for Feifel, Feifel's expert report deals with a set of treatment method claims that does not include claim 4 of the '486 patent, although it does include claim 1. (Feifel Rpt. ¶ 29.) Feifel states that oral drugs containing amphetamine compounds, including amphetamine salts, had been used to treat ADHD for many years.[8] (Id. at ¶ 45.) Feifel states that certain method claims would have been obvious over AU '168, and lists the specific claims he is addressing; the list does not include any claims from the '486 patent. (Id. at ¶ 87.) Feifel states that certain method

[8] This appears to be the one fact that forms the foundation of Defendants' argument that the method of claim 4 is obvious: it was well-known that amphetamine compounds can be used to treat ADHD. The problem is that, without more, this is an "obvious to try" argument. On that basis, it would be obvious to try every possible amphetamine compound as a treatment for ADHD. Defendants have not even suggested that the set of all possible amphetamine compounds can be said to be a "finite number of identified, predictable solutions." KSR, 550 U.S. at 421.

claims would have been anticipated by AU '168, and lists the specific claims he is addressing; the list does not include any claims from the '486 patent. (Id. at ¶ 87.) Feifel's report does not include claim 4 of the '486 patent within its scope. Defendants, however, try to get around this fact by pointing to this deposition statement from Feifel:

> As Defendants' expert Dr. Feifel explained, "[t]o the extent that the mesylate salt . . . is listed in the claims and to the extent that I rely on other experts . . . my opinions may thereby include the mesylate salt." (Feifel Decl. Ex. C, 166:12-18.)

(Defs.' Supp. Rule 56.1 Stmt. ¶ 89.) This statement is not sufficient to transform Feifel's expert report from a report which does not include claim 4 within its scope into a report which does. Feifel's deposition statement does not even rise to the level of a conclusory statement of obviousness. Neither Atwood nor Feifel explained how the method for treating ADHD using lisdexamfetamine dimesylate disclosed in claim 4 of the '486 patent would have been obvious or anticipated in view of the prior art. "General and conclusory testimony . . . does not suffice as substantial evidence of invalidity." Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1152 (Fed. Cir. 2004). Defendants have not offered evidence sufficient to prove that claim 4 of the '486 patent is invalid due to obviousness or anticipation. As to claim 4 of the '486 patent, Plaintiffs' motion for summary judgment of no invalidity will be granted.

Defendants' opposition to Plaintiffs' motion for summary judgment of no invalidity rests largely on the argument that their expert opinions suffice to raise material disputes sufficient to defeat summary judgment. The Federal Circuit has long recognized that expert opinions may sometimes be well-substantiated, and, at other times, may be purely conclusory and without foundation. When expert opinions are purely conclusory, they cannot defeat summary judgment. Stumbo, 508 F.3d at 1365 ("We have repeatedly held that such cursory conclusions will not

withstand summary judgment.") The Federal Circuit's assessment of such a conclusory opinion is applicable here:

> [T]he expert's testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known . . . how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.

ActiveVideo Networks, Inc. v. Verizon Communs., Inc., 694 F.3d 1312, 1327 (Fed. Cir. 2012). Such is the case here: Defendants rely on conclusory expert opinions of invalidity to prove their case and raise a material factual dispute. As the Supreme Court has stated, the essence of the summary judgment inquiry is this issue: "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-252 (1986). The evidence on invalidity here is so one-sided that Plaintiffs must prevail as a matter of law.

Plaintiffs' motion for summary judgment that claims of the '630, '787, '253, and '486 patents are infringed and not invalid is granted in part and denied in part. As to the issue of invalidity, Plaintiffs' motion is granted, and Judgment will be entered in Plaintiffs' favor that the claims at issue of the '630, '787, '253, and '486 patents are not invalid. As to the issue of infringement, as to the ANDA Defendants, Plaintiffs' motion is granted, and Judgment will be entered in Plaintiffs' favor that the ANDA Defendants have infringed the compound claims at issue of the '630, '787, '253, and '486 patents. As to the issue of inducement of infringement, as to the ANDA Defendants, Plaintiffs' motion is granted, and Judgment will be entered in Plaintiffs' favor that the ANDA Defendants have induced infringement of the method claim at issue, claim 4 of the '486 patent. As to the issue of infringement, as to JM, as to the issue of

JM's direct infringement of the compound claims, Plaintiffs' motion is denied. As to the issue of infringement, as to JM, as to the issue of JM's inducement of infringement of the compound claims, Plaintiffs' motion is granted, and Judgment will be entered in Plaintiffs' favor that JM has induced infringement of the compound claims at issue of the '630, '787, and '253 patents.

CONCLUSION

For the reasons stated above, the motions are decided as follows: 1) the motion for partial summary judgment of anticipation of claims 1, 2, and 5 of U.S. Patent No. 7,662,787 by Defendants is denied for lack of subject matter jurisdiction; 2) Defendants' motion for partial summary judgment of noninfringement is granted; 3) Defendants' motion for partial summary judgment of invalidity under 35 U.S.C. § 101 is denied; 4) Defendants' motion for partial summary judgment of no willful infringement is granted; 5) the motion for partial summary judgment of no indirect infringement by Defendants Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials is denied; and 6) Plaintiffs' motion for summary judgment that claims of the '630, '787, '253, and '486 patents are infringed and not invalid is granted in part and denied in part.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: June 23, 2014